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09/652,001	08/31/2000	Alan Krasberg	P56156	2933

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Suite 300
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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/652,001

Applicant(s)

KRASBERG, ALAN

Examiner

Joseph F Weiss Jr.

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J.W.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13, 15-22, 24-29, 31-33, 35-50 and 53-70 is/are pending in the application.
- 4a) Of the above claim(s) 16, 18-22, 24-28, 31, 33, 35-50, 53-57, 64 and 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13, 15, 17, 29, 32, 58-63, 65-68 and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of species H in Paper No. 9 is acknowledged. The traversal is on the various ground(s) that species are not mutually exclusive is not persuasive. (Please note that applicant has cited mere non-binding guidelines in the MPEP and not cited any form of binding authority, the examiner is bound by 35 USC 101 as interpreted by the courts that one invention merits one patent, despite whatever hopes applicant desires in asserting that a multitude of inventions are actually a single invention). This is not found persuasive because as in the words of the Honorable Judge Giles Southerland Rich patentability can be based upon an alternative and different way of achieving the same end. All of the species, including a adjustment for applicant's overly broad interpretation of what constitutes species H, are patently distinct inventive applications or different means by which to achieve the same end, the reduction of free radicals and wherein such differences in language must be accorded patentable weight, they must be given their due respect as distinct inventions. Beyond the use of different claim language, the language sets forth elements that reside in completely different classes, thus meeting the non-binding mutual exclusivity test applicant cites. The classification system is an articulation by the USPTO what is deemed to be categorically distinct in regards to patentability. If applicant is arguing that all these different alternative means/ways of reaching a given end, despite being categorically distinct in accordance with the USPTO classification system, are not patently distinguishing, then such is viewed as an admission on the record that these

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permutations would all be rendered obvious over the prior art if just one was found. The examiner requests that applicant stipulate on the record that such things as an HVAC system in a building are obviously interchangeable with helmets, various types of respiratory circuits etc and to provide evidence to this effect from the perspective of one of ordinary skill in the art, e.g. a sworn affidavit by inventors in the field that a helmet and a building HVAC system are interchangeable. Otherwise, the requirement is still deemed proper and is therefore made FINAL, in accordance all the claims that bring in additional structures of exposure are restricted out, all of which fit under the other species listed. (Please use canons of construction as a guide when given a list of species in the future to expedite prosecution and if any doubts exist or if gaps exist in the coverage of a restriction of this nature then it is advised that applicant call the examiner to address the gaps). Applicant's remedy for any further concerns over the propriety of the restriction can be raised via the petition process.

2. This application contains claims 16, 18-22, 24-28, 31, 33, 35-50, 53-57, 64 & 69 are drawn to inventions nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Species H consists of claim 8-13, 15, 17, 29, 32, 58-63, 65-68 & 70. An action on the merits with regard to species H is noted below, which is an exposure regiment free of structure, i.e. use of a gaseous environment.

Claim Objections

3. Claim 65 objected to because of the following informalities: Line 5 of the claim "breathable" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-13, 15, 17, 29, 32, 58-63, 68 & 70 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Applicant asserts that the use of alkane or hydrogen based fuel gases serve to protect animal tissue from oxygen free radical damage via oxidative reactions, however this is contrary to how the reaction occurs in tissue. Phillips US reference 6254547 outlines the oxygen free radical process in tissue. (See also 6312390, 6221026, & 5996586). The teaching discloses that alkanes (saturated hydrocarbons) are the by- products of reactive oxygen species interactions and that unsaturated hydrocarbons are what are reactive with oxygen free radicals. Applicant's written description is devoid of how a compound that is already at its highest level of oxidation could be further oxidized to neutralize an oxygen free radical. Therefore the invention is inoperative.

In regards to the use of hydrogen, Phillips discloses that hydrogen is actually involved in the creation of oxygen free radicals and not the elimination of such. Applicant's written description is devoid of how a compound that is involved in a reaction that creates an oxygen free radical, can help to protect tissue from oxygen free radicals. Therefore the invention is inoperative.

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In regards to claims 61 & 70, the invention is inoperable, applicant is asserting presentation of the same gas composition in both hyperbaric and hypobaric conditions, and the gas composition cannot be delivered at the same instant in time under two completely opposite conditions.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 8-13, 15, 17, 29, 32, 58-63, 68 & 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description is devoid of these method steps being exclusively performed on land. Furthermore the written description is devoid of any disclosure how providing gaseous materials that either assist in the creation of oxygen free radicals or are the fully oxidized by products of free radical chemistry can still somehow be oxidized further to protect tissue.

7. Claims 8-13, 15, 17, 29, 32, 58-63, 68 & 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as

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to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The written description is devoid of any disclosure to enable one to protect tissue from oxygen free radicals by providing gaseous materials that actually either assist in the creation of oxygen free radicals or are the fully oxidized by products of free radical chemistry can still somehow be oxidized further to protect tissue.

8. Claims 8-13, 15, 17, 29, 32, 58-63, 68 & 70 are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based upon.

The written description is devoid of any disclosure to a best mode as to how one protects tissue from oxygen free radicals by providing gaseous materials that actually either assist in the creation of oxygen free radicals or are the fully oxidized by products of free radical chemistry can still somehow be oxidized further to protect tissue.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 8-9, 15 & 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Stamler (US 6314956).

In regards to claim 8, Stamler discloses a method to provide protection from reactive oxygen free radicals species, the method comprises preparing a breathable

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composition comprising oxygen intentionally supplemented with a fuel gas (note the use of ethyl nitrite in breathing gas), providing said breathable composition to an animal on land while the animal is surrounded by a gaseous environment and within said animal, oxidizing said reactive oxygen species with said fuel gas.

In regards to claim 9, Stamler discloses the use of a human.

In regards to claim 15, Stamler discloses the use of an explosive composition (Ethyl Nitrite).

In regards to claim 17, the pressure of the gas of Stamler is provided at or "near" atmospheric pressure.

In regards to claims 29 & 63, the gas of Stamler is breathable, deliverable with ambient air.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler.

In regards to claim 32, the delivery of gas as a rate to insure the gas is delivered at a rate that will insure a desired concentration, e.g. therapeutic, is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary.

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13. Claims 10, 13 & 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler in view of Deluza (WO 96/06771).

In regards to claims 10, Stamler substantially discloses the instant application's claimed invention, but does not explicitly disclose exposure as greater than an hour. However, Deluza disclose such (exposure discloses as greater than an hour (page 6 lines 3-10)). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Deluza and used them with Stamler. The suggestion/motivation for doing so would have been to improve the reduction of free radical injury by increasing contact time. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 13, Stamler substantially discloses the instant application's claimed invention to include the use of hydrocarbon-based free radical reducing gases, but does not explicitly disclose the use of hydrogen. However, Deluza disclose such (See Abstract). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features

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of Deluza and used them with Stamler. The suggestion/motivation for doing so would have been because such are interchangeable equivalents. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 61, Stamler substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of hyperbaric conditions. However, Deluza disclose such (Page 7 lines 15-20). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Deluza and used them with Stamler. The suggestion/motivation for doing so would have been to enhance perfusion of the gas into the user's system. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

14. Claims 11-12, 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler & Deluza as applied to claim 10 above, and further in view of Gardner et al (Spacecraft Maximum Allowable Concentrations for Selected Airborne Contaminants, Vol. 1, 1994).

In regards to claims 11-12, 58-60, Stamler & Delauze substantially discloses the instant application's claimed invention, but does not explicitly disclose exposure for greater than a day or greater than a month. However, Gardner discloses such (see exposure charts for hydrogen & methane on pages 140 & 145 respectively). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Gardner and used them with the invention suggested by Stamler & Delauze. The suggestion/motivation for doing so would have been to expose the user to the gas over a given & proscribed time period for study, analysis and evaluation. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claims 58-60, applicant's variation of gas exposure regimentation all fall within the range of the time frame of the teaching which is old and well known in the

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art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Furthermore, it is noted that applicant's specification does not set forth these obvious variations of exposure regimen, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

15. Claims 62, 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler as applied to claim 8 above, and further in view of Scherer et al (US 5971934).

In regards to claims 62 & 65, Stamler substantially discloses the instant application's claimed invention to include the use of hydrocarbon-based free radical reducing gases, but does not explicitly disclose the use of acetylene. However, Scherer discloses such (Col. 2 lines 29-42). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Scherer and used them with Stamler. The suggestion/motivation for doing so would have been because such are interchangeable equivalents. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 66, the gas of Stamler is breathable, deliverable with ambient air.

In regards to claim 67, in regards to the use of a second fuel gas (note applicant defined acetylene as a fuel gas) the prior art references used substantially disclose the claimed invention except for the duplication of a known part for a known purpose, i.e. the use of two fuel gases instead of one fuel gas.

It is noted that applicant's specification does not set forth this duplication of a known part for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 68, the reference noted above substantially disclose the claimed invention to include the use of hydrocarbon based oxygen free radical reducing gases but does not disclose the use of the specific gases of methane, ethane or propane, interchangeable equivalents to the gas Stamler does disclose (because it does the same thing applicant asserts his gases do, reduce free radicals).

It is noted that applicant's specification does not set forth these, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

16. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler & Scherer as applied to claims 65 & 67 above, and further in view of Deluza.

In regards to claim 68, the suggested device substantially discloses the instant application's claimed invention to include the use of hydrocarbon-based free radical reducing gases, but does not explicitly disclose the use of hydrogen. However, Deluza disclose such (See Abstract). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Deluza and used them with the suggested device. The suggestion/motivation for doing so would have been because such are interchangeable equivalents. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary.

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17. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler & Deluza as applied to claim 61 above, and further in view of Kotliar (US 5964222).

In regards to claim 70, the suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of a hypobaric environment. However, Kotliar disclose such (See e.g. Abstract). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Kotliar and used them with the suggested device. The suggestion/motivation for doing so would have been because to more effectively ventilate the user's lungs to insure optimal gas absorption. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 6254547, 6312390, 6221026, 5996586

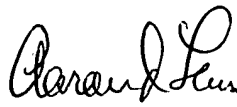
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


J. J. Weiss
11/12/03


Aaron J. Lewis
Primary Examiner